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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/822,251

04/09/2004

Richard C. Gunderson

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EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,251	<b>Applicant(s)</b> GUNDERSON ET AL.	
	<b>Examiner</b> Eric Blatt	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-19-2004; 10-27-2004; 11-05-2004; 12-15-2004; 5-</u>         | 6) <input type="checkbox"/> Other: _____                          |
| <u>24-2006; 8-21-2006; 11-7-2007.</u>  |   |



## **DETAILED ACTION**

### ***Claim Objections***

Claim 21 is objected to because of the following informalities: claim 21 recites "configure to" wherein it appears to intend "configured to." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 recites the limitation "the retainer." There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-12, 20-23, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Tran et al. (US 2002/0151955).

Regarding claims 1-4, 6-9, 34-37, Tran discloses an implantable medical endoprosthesis bumper 118 (Figures 2-7) having a retainer 120 configured to

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interdigitate with a cell of an implantable medical endoprosthesis to unidirectionally position the implantable medical endoprosthesis with respect to the bumper. The implantable medical endoprosthesis bumper 118 includes a bumper body, and the retainer 120 protrudes radially from the bumper body. The retainer 120 comprises a flap 120 that protrudes radially from the bumper body. The retainer 120 comprises a hook, a spike, or a barb. The retainer is capable of flexing to interdigitate with the cell or to disengage from the cell. (Figures 8a-8c, Paragraphs 7-11) The retainer 120 is configured to interdigitate with a cell of an implantable medical endoprosthesis to unidirectionally position the implantable medical endoprosthesis with respect to the bumper or to disengage from the cell. There is a catheter 108 and a sheath 114 at least partially surrounding the catheter 108, and the endoprosthesis 124 is disposed therebetween. (Figure 1)

Regarding claims 10-12, Tran discloses a method of positioning an implantable medical endoprosthesis on a catheter (Figures 8a-8c), the method comprising: unidirectionally positioning the implantable medical endoprosthesis 124 with respect to the catheter 108 without reducing a diameter of the implantable medical endoprosthesis 124. As seen in the steps illustrated in Figures 8a-8c, the endoprosthesis 124 is positioned without recuding the diameter of said endoprosthesis 124. The catheter 108 comprises a bumper 118 including a retainer 120 configured to interdigitate with a cell of the implantable medical endoprosthesis. The catheter 108 comprises a catheter body 108, 118 including a retainer 120 configured to interdigitate with a cell of the implantable medical endoprosthesis.

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Regarding claims 20-23, Tran discloses a method of positioning an implantable medical endoprosthesis on a catheter (Figures 8a-8c), the method comprising: moving the implantable medical endoprosthesis 124 in a longitudinal direction of the catheter 108 to interdigitate a cell of the implantable medical endoprosthesis 124 with the catheter without reducing a diameter of the implantable medical endoprosthesis 124. The cell is the open center of the endoprosthesis 124. Said cell is interlocked with the catheter 108. The catheter 108 comprises a bumper 118 including a retainer 120 capable of interdigitating the cell of the implantable medical endoprosthesis. The bumper 118 includes a bumper body 118, and the retainer 120 protrudes radially from the bumper body 118. The catheter 108 comprises a catheter body 108, 118 including the retainer.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-18, 24-26, 28-33, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tran et al. (US 2002/0151955) in view of Gunderson et al. (US 2002/0120321).

Regarding claims 13-18, 24-26, 28-33, and 38-39, Tran discloses all elements of said claims as previously discussed except that the stent has an open cell and the retainer is interdigitated with said open cell. Gunderson discloses a stent having a plurality of flexible open cells wherein protrusions 50 are interdigitated with said cells to retain the stent on the delivery apparatus. (Figure 5) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Tran by providing a stent with flexible open cells and having the retainer interdigitate with said cells in order to better retain the stent on the delivery apparatus as taught by Gunderson. Additionally, it would have been obvious to flex the cells upon interdigitating said cells with the retainer in order to provide a tight fit in order to better retain the stent.

Regarding claim 18, the interdigitating step involves the retainer being expanded from a first radial size to a second radial size. (Figures 8a-8c)

Regarding claim 28, the retainer is radially expanded.

Regarding claim 29, the retainer comprises a shape memory material. (See Abstract)

Regarding claim 30, Tran does not disclose that the retainer comprises a swellable material. The protrusions 50 of Gunderson are formed on the balloon and expand into the open cells to retain the stent. Said protrusions 50 comprise a swellable material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Tran by having the retainer comprise a swellable

material in order to have the retainer expand into the open cells to retain the stent as taught by Gunderson.

Regarding claim 31, the implantable medical endoprosthesis is disposed over the retainer prior to expanding the retainer. (Figures 8a-8c)

Regarding claims 38 and 39, the modified apparatus comprises an implantable medical endoprosthesis having first and second ends along a longitudinal direction, and a plurality of cells including a partially open cell located at the first end, wherein the partially open cell is capable of flexing in a plane parallel to the longitudinal direction. The partially open cell is capable of interdigitating with a retainer of a stent bumper.

Claims 5, 19, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tran et al. (US 2002/0151955) in view of Gunderson et al. (US 2002/0120321) as applied to claims 13-18, 24-26, 28-33, and 38-39 above and further in view of Deem et al. (US 6,231,597).

Regarding claims 5, 19, and 27, Tran in view of Gunderson teach all elements of said claims as previously discussed except that the retainer comprises a wax and interdigitating a cell of the implantable medical endoprosthesis with the retainer comprises molding the wax to extend into the cell. Deem teaches that a low temperature biocompatible wax may be used to releasably retain a stent on a delivery apparatus. (Column 7, Lines 19-32) It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus of Tran by having the retainer comprise a wax in order to releasably retain the stent on the delivery



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apparatus as taught by Deem. Since Gunderson teaches having the retainer extend into a cell of the stent, upon using the wax as adhesive to retain the stent on the retainer as taught by Deem, it would have been obvious to have the step of interdigitating said cell with the retainer comprise molding the wax to extend into the cell.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Hayashi; Reid (US 6280464): Prosthesis gripping system and method
- Wright; Michael T. et al. (US 7264632): Controlled deployment delivery system
- Mareiro, Wayne et al. (US 20030114915): Stent security balloon/balloon catheter
- Kusleika, Richard S. (US 20030176909): Everting stent and stent delivery system

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Blatt  
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/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731